URINE SPECIMEN COLLECTION PROCEDURES GUIDELINES

49 CFR PART 40

FOR TRANSPORTATION WORKPLACE
DRUG TESTING PROGRAMS

U.S. Department of

Transportation

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INTRODUCTION

The Department of Transportation's (DOT) operating administrations (Federal Aviation Administration, Federal Highway Administration, Federal Railroad Administration, United States Coast Guard, Federal Transit Administration, and Research and Special Programs Administration) have issued regulations requiring anti-drug programs in the aviation, highway, railroad, maritime, mass transit, and pipeline industries. Employers regulated by the U.S. Coast Guard (maritime industry) and Research and Special Programs Administration (pipeline industry) are not required to conduct urine collections using the "split specimen" procedures. Where applicable, the differences in collection procedures are identified in these guidelines.

The DOT operating administrations' rules require that employers conduct drug testing according to provisions of 49 CFR Part 40, "Procedures for Transportation Workplace Drug Testing Programs," Final Rule, published in the Federal Register on December 1, 1989 (54 FR 49854), revised on February 15, 1994 as "Procedures for Transportation Workplace Drug and Alcohol Testing Programs" (59 FR 7340) and amended on August 19, 1994 (59 FR 42996). The procedures in 49 CFR Part 40 are based on the Department of Health and Human Services' "Mandatory Guidelines for Federal Workplace Drug Testing Programs," published in the Federal Register on April 11, 1988 (53 FR 11970) and revised on June 9, 1994 (59 FR 29908).

The procedures for collection of urine under these rules are very specific and must be followed whenever a DOT required urine collection (for a drug test) is performed. The only exception is the Federal Railroad Administration's Post-Accident Toxicological Testing Program in which the collector will be provided specific instructions and a testing kit by the railroad representative. These procedures (including the mandatory DOT custody and control form) apply only to DOT required testing. While employers can use these procedures for testing under employer or state authority, they are not required by Federal regulations to do so.

The collector is key to the success of any drug testing program; he/she is the one individual with whom all donors will have direct, face-to-face contact. Without the collector assuring the integrity of the specimen and collection process, the test itself cannot be valid. Without the collector's sensitivity to an individual's privacy, the entire testing program is subject to criticism. It is imperative that all collectors fully understand and follow these procedures.

There may be intermediaries, such as consortia, contractors, clinics, or doctors, who act as agents of the employer and who conduct collections. While an employer can contract for such functions, an employer may never contract away his/her responsibilities under the DOT rules. Ultimately, it is the employer who must make sure that the procedures are understood and followed in each and every urine specimen collection performed under the DOT regulations.

This guide, together with 49 CFR Part 40, the DOT operating administrations' rules, and the employer's company anti-drug program, will provide a collector with the information needed in the performance of his/her duties.

> Information appearing throughout this document surrounded by a double lined box provides additional clarification regarding these procedures or addresses specific or unusual circumstances that may arise during the collection process. Since the majority of the DOT industry will be using the split specimen collection procedure, all references to specimen bottles and labels/seals are made in the plural with the understanding that for single collection procedures, the reference should be in the singular.

Note: This document provides an updated overview of the urine collection procedures required by the DOT drug and alcohol rules (49 CFR Part 40) published on February 15, 1994 and amended on August 19, 1994. The information in this document addresses the normal collection procedures and provides examples of some of the more common problems or situations encountered. However, information contained in this publication should not be used to interpret the legal requirements of the actual rules.

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Previous editions are obsolete

Section I - The Collector

The collection site person performs essential steps in conducting a Department of Transportation (DOT) mandated urine specimen collection for drug testing. The employer must designate the personnel responsible for conducting specimen collections in accordance with 49 CFR Part 40, which defines a collection site person as "a person who instructs and assists individuals at a collection site and who receives and makes a screening examination of the urine specimen provided by those individuals." This individual will be referred to as the "collector" in these guidelines. The following personnel may serve as collectors:

1. A company employee who has received training in the DOT procedures.

2. Non-medical personnel contracted by the employer to conduct collections, who have been trained in the DOT procedures.

3. Medical personnel (nurses, medical technicians, physicians, physician's assistants or other state recognized medical professionals) who have been provided with instructions for the DOT procedures.

The donor must not be the collector of his/her own urine specimen. The supervisor of the donor should not serve as the collector unless there is no feasible alternative. (Some DOT operating administrations do not permit the supervisor to act as a collector under any circumstances).

In general, an employee who is in a safety-sensitive position and subject to the DOT drug testing rules should not be a collector or an observer for co-workers who are in the same testing pool or who work together with that employee on a daily basis. This is to preclude any potential appearance of collusion or impropriety.

When the collection is observed, the collector (whether a medical person or not) must be the same gender as the donor. There is no exception to this requirement. When a collection is conducted at a site that provides less than complete privacy for the donor (e.g., a stall or other partially private enclosure) and the collector is a non-medical person, then the collector must be the same gender as the donor (this is a "monitored" collection under 49 CFR Part 40.23(d)(4)). Non-medical personnel may serve as collectors for male and female donors only when a private toilet with a full enclosure is used.

Instructions on the DOT procedures must be available at the collection site for reference by the collector. Instructions/checklist outlining donor responsibilities should also be provided to the donor at the time of collection or during a training program.

Section II - The Collection Site

The employer or employer's agent must designate a collection site(s) for the purpose of collecting urine specimens using procedures prescribed in 49 CFR Part 40. A collection site must at a minimum provide:

1. An enclosure where privacy for urination is possible;

2. A toilet for urination (unless a single use (disposable) container is used with sufficient capacity to contain the void);

3. Source of water for washing hands;

4. Suitable writing surface for completing the required paperwork (custody and control form documents); and,

5. Restricted access so that the site is secure during collection.

Any of the following could serve as a collection site provided they meet the minimum requirements listed above:

1. Employee restroom

2. Patient toilet at doctor's office/hospital/clinic

3. Portable toilet facility

4. Employee office/breakroom

5. Hotel/motel restroom

6. Restroom with open urinals

7. Public restroom

8. Mobile collection site (e.g., a van)

9. Any other area that meets the above minimum requirements.

A secure collection site means:

1. Restricting access to the site to un-authorized personnel.

2. Restricting access to collection materials/supplies and the specimens.

3. Prohibiting unobserved entrance to/exit from the site.

4. Providing for secure handling/storage of specimens from collection until shipment.

The collection site should not provide the donor any access to materials that could be used to adulterate the specimen. The collector should always take any trash, used bottles, collection containers, discarded forms or any other collection related materials for disposal away from the collection site. Items that donors could use for adulteration include but are not limited to:

1. Soap, disinfectants

2. Cleaning agents

3. Personal hygiene products

4. Discarded specimen containers

5. Beverages

6. Water (hot and cold)

7. Contents of trash cans

> Where a pre-designated employer's site is not available (under post-accident or reasonable suspicion testing, for example), the collector should secure the site as described by limiting access to the site, ensuring bluing is in the toilet bowl, and limiting access to water.

In final preparation of the site, the collector should shut off or otherwise effectively secure any sources of water. This includes any adjacent area to which the donor may have access prior to handing the specimen to the collector.

The water supply available in the toilet/restroom must be controlled to discourage the donor from diluting/adulterating the specimen. Whenever possible, bluing agents must be added to any tank and/or toilet bowl or other water supply accessible to the donor. The following are acceptable ways to control the water supply:

1. Tape faucets prohibiting flow of water.

2. Use shut off valve to cut off water supply.

3. Faucets and sink located outside the toilet area which are under control of the collector do not have to be taped.

Section III - Collection Supplies

Once a site has been selected, the collector should ensure that he/she has the appropriate materials to conduct a proper collection. The supplies necessary for conducting a urine specimen collection under DOT procedures are:

1. Two (2) clean, single-use specimen bottles with caps or lids, securely wrapped or sealed in a protective cover. Under single specimen collection procedures, only one (1) bottle is required. In either case, the collector should carry additional specimen bottles (or extra kits) in case a collection involving a "shy bladder" occurs.

> DOT recommends that the bottles and collection container be wrapped separately. This will increase the ease of the collection process and prevent potential problems or challenges by the donor.

2. A clean, single-use, wrapped or sealed collection container for the donor to urinate into. Use of the collection container is optional, but highly recommended if the specimen bottle neck or opening is small. It is also recommended that the collection container (into which the specimen is initially deposited) have affixed to it a temperature strip from which a temperature reading of the urine can be obtained.

> If a collection container is not used, the specimen bottle into which the donor will urinate must have a temperature strip affixed for reading the temperature of the specimen. In the case where the collection container or the specimen bottle does not contain a temperature strip or does not seem to work properly, the collector must take the specimen temperature with a thermometer that has a sterile sleeve or other methodology to preclude possible contamination of the specimen. This thermometer should not be used to also take the donor's body temperature.

3. An oral thermometer which the collector can use if the temperature of the specimen is outside of the range listed in 49 CFR Part 40 (32^{o}-38^{o}C/90^{o}-100^{o}F), as amended on August 19, 1994.

4. The DOT custody and control form with pre-printed specimen I.D. number.

5. Tamper-evident unitary labels/seals for the specimen bottles, that includes the same pre-printed specimen I.D. number that appears on the custody and control form, and a place for the donor's initials and the date (this should be part of the custody and control form listed in 4 above).

6. A tamper-evident shipping container label/seal with space to allow for the collector's initials and date.

7. A shipping container which can be labeled for transporting the specimen to the laboratory and which can be sealed with a tamper-evident seal.

8. Bluing agent to add to the toilet bowl or tank to discourage adulteration/dilution of the specimen.

9. Appropriate collector identification. The collector is required to provide his/her identification (or collection company identification) if requested by the donor. There is no requirement for the collector to have a picture I.D. or to provide his/her driver's license with an address. Also, the collector is not required to provide any certification or other documentation to the donor proving the collector's training or skill in the DOT collection process.

Although not required, it would benefit the collector to have the employer representative's name and telephone number to call should unusual situations arise during the collection process.

The DOT recommends collectors use sanitary gloves while handling specimens. The Occupational Safety and Health Administration has specific guidelines addressing protection of employees with exposure to potentially infectious body fluids (29 CFR Part 1910.1030).

Section IV - The Collection

The donor must be positively identified as the individual selected for testing. Acceptable methods of identification are:

1. Photo identification (e.g., driver's license, employee badge).

2. Positive identification by the employer/employer representative.

3. Any identification allowed under an operating administration's rules.

The following are not acceptable ways to identify the donor:

1. Identification by a co-worker or another donor.

2. Non-photo identification cards (e.g., social security card, credit card, union or other membership cards).

3. Pay vouchers, employment papers.

4. Voter or address verification.

Exception: If the donor is self-employed and has no photo identification, the collector should notify the collection site supervisor and record in the remarks section that positive identification is not available. The donor must be asked to provide two items of identification bearing his/her signature. Proceed with the collection. When the donor signs the certification statement, compare the donor's signature with signatures on the identification presented. If the signatures appear consistent, continue the collection process. If the signature does not match signatures on the identification presented, make an additional note in remarks section stating that "signature identification is unconfirmed."

When the donor does not have appropriate identification this should not be considered a refusal. The collector should remember that his/her primary function is to obtain a specimen that can be tested for drugs under DOT rules. The collector should provide sufficient information in the remarks section to help the MRO make a determination regarding the merit of the collection process or for the employer to determine if there are systemic problems or other shortfalls in their policy/program.

Section V - Collection Steps

The following 23 steps summarize the collection procedures for collection of urine specimens under the DOT rules. Changes in the sequence of the procedures, errors, or omissions in some of the steps may result in a specimen being unacceptable for testing at the laboratory or the results being declared invalid upon review by the MRO.

1. After verification of the identification of the donor, the collector completes the following steps/blocks on the custody and control form:

a. Employer's name, address and employer I.D. number (**Custody and Control Form, Step 1**) if applicable (may be pre-printed).

b. Medical review officer (MRO) name and address (may be pre-printed).

> A specific physician's name and address must appear on the form rather than the name of the clinic or medical facility.

c. Drugs the specimen will be tested for.

d. Type of test (e.g., random, pre-employment, etc.).

e. Donor's I.D. number (i.e., social security number, badge number or other employee number).

2. The collector asks the donor to remove any unnecessary outer clothing (coat, jacket, hat, etc.) and to leave briefcase, pocketbook, bookbag or other personal belongings he/she is carrying with the jacket/coat. The collector provides a receipt for any personal belongings when requested by the donor and secures the items during the collection.

3. The donor must <u>not</u> be asked to empty his/her pockets or remove other articles of clothing such as shirts, pants, dresses, underwear, nor should he/she be requested or required to use a hospital or examination gown.

However, if a collector, during the course of a collection procedure, notices any unusual behavior that indicates a donor may attempt to tamper with or adulterate a specimen (for example as evidenced by a bulging or overstuffed pocket), the collector may request that the donor empty his/her pockets, display the items, and explain the need for such items at the collection. This procedure may be done only when individualized suspicion exists that an individual may be about to tamper with or adulterate a specimen. Otherwise, requiring donors to empty their pockets as a common practice is not permitted under the DOT rules.

4. The collector instructs the donor to wash and dry his/her hands, preferably under the collector's observation. The donor should not be allowed any further access to water or other materials that could be used to adulterate/dilute the specimen.

5. The collector provides the donor a wrapped/sealed collection container and/or specimen bottles. Either the collector or the donor may unwrap or break the seal of the container/bottles; however, if the collector unwraps the collection container/bottles, he/she need to do so in the donor's presence. If the collection container is wrapped separately from the specimen bottles, only the collection container should be unwrapped at this time. The specimen bottles should be unwrapped when the donor gives the specimen in the collection container to the collector. (DOT strongly recommends that collectors use kits that have the collection container and specimen bottles wrapped separately).

6. Under split specimen procedures, if the two bottles and the collection container are wrapped together, the collector should let the donor take the collection container and the two bottles and lids with him/her into the restroom. If there is no collection container and the donor will be providing the specimen into one of the bottles (and both are wrapped together), the donor should take both bottles and lids into the restroom. As indicated previously, DOT recommends that the collection container and the specimen bottles be wrapped separately.

7. In a single collection method, if the bottle and the collection container are wrapped together, the donor should take both into the restroom. If the kit contains two (2) bottles, the collector can dispose of the unused bottle (away from the collection site). If the extra bottle is returned in the kit to the laboratory, the laboratory may interpret this to be a split collection in which the split was not collected (unless a comment is made to this effect in the remarks section).

> Employers regulated by the Federal Highway Administration (FHWA), Federal Aviation Administration (FAA), Federal Transit Administration (FTA), and Federal Railroad Administration (FRA) must use the split specimen method of collection (2 bottles). Employers regulated by the Research and Special Programs Administration (RSPA) or the U.S. Coast Guard (USCG) may use either method of collection.

8. The collector accompanies the donor to the restroom where the donor will provide the specimen. The donor enters the restroom and shuts the door; the collector remains outside the closed door.

> If only a multiple stall restroom is available (e.g., following an accident or reasonable suspicion determination) , the collector must add bluing agent to all the toilets and ensure that the donor does not have access to water. If the collector remains in the immediate area (outside a restroom stall), this is considered a monitored collection and must meet the requirements of 49 CFR 40.23(d)(4) (i.e., non-medical personnel must be of the same gender as the donor).

9. The collector receives the specimen from the donor. Both the collector and donor must maintain visual contact of the specimen until the labels/seals are placed over the bottle caps (see Step 13 below).

10. The collector checks the specimen and:

a. Reads the specimen temperature within 4 minutes of receiving the specimen. If the specimen is provided into a collection container, the temperature is read from the temperature strip affixed to the collection container. If the specimen is provided directly into a specimen bottle, the temperature is read from the temperature strip affixed to the specimen bottle.

> The DOT rules require that the temperature of the urine specimen be taken within 4 minutes of urination. The collector must ensure that procedures for receiving the specimen from the donor fall within this time requirement.

If the collection container does not have a temperature strip affixed to it, the collector should pour the specimen into a urine specimen bottle and read the temperature from the temperature strip affixed to the bottle. If neither the collection container nor the bottle(s) contain a temperature strip, the collector must use a thermometer to determine the specimen's temperature (in either case, within four minutes). It should be noted that the DOT strongly recommends that collection kits have a temperature measuring system that utilizes the use of a temperature measuring strip.

b. Checks/marks the box on the custody and control form if the temperature is in range (32^{o}-38^{o}C/90^{o}-100^{o}F) or records the actual temperature on the custody and control form (**Custody and Control Form, Step 2**).

c. Checks specimen volume to ensure there is at least 45 ml. If this is a single specimen collection (not a split), a minimum of 30 ml is required.

d. Inspects the specimen for unusual color, odor, or other signs of adulteration.

If the donor's specimen is not within the acceptable range of 32^{o}-38^{o}C/90^{o}-100^{o}F, the collector shall offer the donor an opportunity to have his/her oral temperature taken. If the donor's body temperature is within 1^{o}C/1.8^{o}F of the specimen, the collector should annotate this in the remarks section and continue the collection process. If the individual's body temperature varies by more than 1^{o}C/1.8^{o}F from the specimen's temperature, then there is reason to believe that the sample may have been adulterated or substituted. The collector shall complete the custody and control form for this specimen and shall write in the remarks section the donor's actual temperature. The collector shall obtain, in advance of the direct observation collection, the review and concurrence of the collection site supervisor or the designated employer representative that the facts support the decision and requirement to conduct a direct observation collection. Any <u>required</u> second collection under direct observation should be conducted before the donor departs the collection site. Both specimens shall be sent to the laboratory.

If it is apparent on visual inspection that the donor has adulterated the specimen (e.g., blue dye is in the specimen), the collector <u>shall</u> proceed to collect a specimen under direct observation following the above steps.

11. The collector pours at least 30 ml of specimen from the collection container into a specimen bottle, which will be designated as the primary or "A" bottle. The remaining specimen, at least 15 ml, is then poured into a second bottle, which will be designated as the "split" or "B" bottle.

12. If a specimen bottle is used by the donor to provide a specimen, the collector pours at least 15 ml into the second bottle, which is designated as the split or "B" bottle. The original bottle (into which the donor provided the specimen) becomes the primary or "A" bottle. The collector should make sure that at least 30 ml (or more) remains in this bottle.

13. The collector immediately places lids/caps on the specimen bottles then applies tamper-evident labels/seals (**Custody and Control Form, Step 3**).

14. The collector dates labels/seals. The donor is then requested to initial the labels/seals which are now on the specimen bottles (**Custody and Control Form, Step 3**). At this point, since the specimen bottles are sealed with tamper-evident tape and do not have to be under the donor's direct observation, donor is allowed to wash his/her hands if he/she desires to do so.

15. The donor reads and completes the donor certification section on Copy 4 of the form (**Custody and Control Form, Step 4**) by signing the certification statement, providing his/her date of birth, printed name and a contact phone number. (This is a good point at which to remind the donor about his/her option to list prescriptions and over-the-counter medications he/she may have recently taken on the back of the donor copy of the custody and control form but not on any other copy.)

> If the donor refuses to sign the form, the collector must make a notation in the remarks section to that effect. Otherwise, without the collector's comment, a chain of custody and control form without the donor's signature could result in a fatal flaw. The same procedure should be followed if the donor refuses to initial the labels/seals.

16. The collector completes the collector certification section of the custody and control form (**Custody and Control Form, Step 5**) by: printing the name and address of the collection facility and the collector's business telephone number; checking the box indicating if this was a split specimen collection; printing his/her name; signing the certification statement; and recording the date and time of the collection.

17. The collector records any remarks concerning the collection in the "remarks" section of the custody and control form.

18. The collector signs in the chain of custody block indicating he/she has received the specimen from the donor, and prints his/her name and the date (**Custody and Control Form, Step 6**). NOTE: The purpose of change entry has been pre-printed and explains the transfer of the specimen from the donor to the collector (provide specimen for testing); donor does not sign anywhere in the chain of custody block.

19. The collector completes the chain of custody "specimen released by" block, signing and printing his/her name and if the specimen is being prepared for shipment to the laboratory, completes the "specimen received by" block by printing the courier or shipment service name and including the date. Collector then completes "purpose of change" section explaining the transfer of the specimen from the collector to the courier or shipment service (i.e., shipment to lab).

STEP 6: TO BE INITIATED BY THE COLLECTOR AND COMPLETED AS NECESSARY THEREAFTER

DATE MONTH DAY YEAR	SPECIMEN RELEASED BY	SPECIMEN RECEIVED BY	PURPOSE OF CHANGE
12 / 5 / 94*	DONOR - NO SIGNATURE**	Signature *Joe Collector* * Name Joe Collector	PROVIDE SPECIMEN FOR TESTING**
12 / 5 / 94*	Signature *Joe Collector* * Name Joe Collector	Signature _____ Name ABC Courier*	SHIPMENT TO LAB*
/ /	Signature _____ Name	Signature _____ Name	

* Cannot be pre-printed.
** Must be pre-printed.

20. The collector gives the donor his/her copy of the custody and control form (Copy 5). The donor may now leave the collection site.

21. The collector prepares the bottles and Copy 1, Copy 2, and Copy 3 (laboratory copies) of the custody and control form (if a split specimen collection) or Copy 1 and Copy 2 only (if a single specimen collection) for shipment, placing them in the shipping container.

22. The collector seals the shipping container and initials and dates the seal on the shipping container.

23. The collector prepares additional copies of the custody and control form for appropriate distribution (Copy 4 to MRO, Copy 7 to employer, Copy 6 for filing by collection facility).

The above 23 steps represent a "typical" collection and are the basic requirements for a DOT mandated urine specimen collection. They are presented in chronological order to represent the proper order for the steps in obtaining, documenting and securing a urine specimen. Following each collection, the collector should check the restroom or collection site to ensure that the donor did not leave anything that could be used by the next donor to adulterate/dilute his/her specimen.

If the specimen will not be shipped immediately, the collector is responsible for ensuring its integrity and security. The shipping container must be under "visual control" of the collector and not left unattended. If the collector is not shipping the specimen directly to the laboratory (e.g., a lapse of time between release by the collector and pickup by the courier), it will be necessary for the sealed specimen (in the sealed shipping container) to be stored in a secure location until shipping can be accomplished.

A secure location means that the specimen is in a locked container with only the collector and/or a limited number of personnel having the key. The container can be a cabinet, locked refrigerator, a special box, or other container that cannot be easily accessed without a key. A less desirable secure location could be a room which is locked and has controlled access. Under these circumstances, documentation has to exist as to who has access (keys) to the container or room. Although not required by DOT rules, the collector should as a matter of good practice, document in a log or on the collector's copy of the chain of custody form, the time the sealed shipping container was put into and removed from temporary secure storage and other pertinent information (reason for storage, place, by whom picked up, etc.).

Couriers, postal employees, and other personnel involved in the transportation of the sealed shipping container are not required to make additional chain of custody entries on the custody and control form (49 CFR 40.25, August 19, 1994).

Section VI - Fatal Flaws

When a DHHS certified laboratory accessions a DOT specimen they will check for fatal flaws in the collection documentation. Any of the following errors or omissions are considered "fatal flaws" and should result in a specimen being rejected for testing by the laboratory:

1. Pre-printed specimen I.D. number on the chain of custody form does not match I.D. number on the bottles.

2. No specimen I.D. number on the bottles.

3. Insufficient quantity of urine for the laboratory to complete testing.

4. Specimen bottle(s) seal is broken or shows evidence of tampering.

5. Specimen is obviously adulterated (i.e. color, foreign objects, unusual odor) and the collector did not collect a second specimen under direct observation.

The following errors or omissions are also considered "fatal flaws" unless they are corrected by signed documentation:

1. No collector's signature on collector certification statement.

2. Incomplete chain of custody block (minimum of 2 signed entries by collector, both dated, and shipping/storage entry). There is no requirement to have the courier sign the chain of custody form.

3. Donor Social Security Number or I.D. number is omitted on the custody and control form, unless "refusal of donor to provide" is stated in the remarks section.

Additionally, specimen test results reviewed by the Medical Review Officer should be canceled (by the MRO) when the following procedural errors occur (unless corrections are made):

1. Donor certification statement is not signed and there is no indication in the remarks section of the donor's refusal to sign.

2. The certifying scientist's signature is omitted on positive results from the laboratory.

"Fatal Flaw" Corrective Action:

The DOT recommends that laboratories retain specimens not acceptable for testing a minimum of five working days. Therefore, if the corrective action is not accomplished within this time, the collection process may not be correctable. The laboratory may contact the collection site or the employer in an effort to obtain signed statements from collection site personnel explaining or correcting procedural errors or omissions. If the employer or collector provides corrective actions (signed statements) which supply the needed information, the laboratory may proceed with analysis of the specimen. Similarly, the MRO may elect to seek corrective actions (signed statements) to supply omitted donor or certifying scientists' signatures.

When a specimen is not tested by the laboratory for reasons outlined above, or the test result is considered invalid by the MRO for reasons outlined above, the test should be canceled and reported as such to the employer. Pre-employment, post-accident (within operating administration's time limits), and return-to-duty fatally flawed collections, should be re-collected (at the direction of the employer or the MRO) because the donor still needs to have a negative test result (pre-employment and return-to-duty) before he/she is allowed to perform safety-sensitive duties.

Section VII - Non-DOT Collection (under Employer's Authority)

If the employer's policy requires applicants/employees to submit to drug testing outside the requirements of the DOT rules, a separate collection process, including a separate void is necessary. The DOT mandated specimen is always collected first. Urine for the employer/company test shall not be poured off from the DOT collection. The donor may not be provided multiple specimen bottles or collection cups and instructed to fill one "for the DOT specimen" and the other "for the company specimen." The custody and control form used for company (Non-DOT) tests must not contain statements concerning Federal regulations or procedures.

Remember for non-DOT collections:

1. DOT collection first.

2. A separate non-DOT collection requires an additional void.

3. Clearly inform donor the separate collection is not required by DOT.

4. Do not use a custody and control form with reference to DOT or Federal regulations/procedures. A "look-alike" form may be used, but without any mention of DOT or Federal procedures.

Section VIII - "Shy Bladder" Collection

If the donor tells the collector when he/she reports for a collection that he/she cannot provide a specimen, the collector should continue the process and request the donor to try to provide a specimen. DOT has provided guidance that the donor demonstrates his/her inability to provide a specimen at the time the donor returns from the restroom to the collector and provides either no specimen or a specimen of insufficient quantity. At this point, the collector should:

1. Annotate on the original custody and control form in the remarks section that an attempt was made with insufficient quantity of specimen and note the time.

2. Discard any inadequate specimen and the bottles/collection container used for the void. Retain the custody and control form.

3. Direct the donor to drink fluids (up to, but not more than 24 fluid ounces) and remain at the collection site. Donor should be under direct observation of the collector or a company representative to prevent the donor from performing actions that would compromise the collection process (drinking excessive fluids, obtaining "clean" urine, obtaining adulterants, etc.).

4. After a reasonable time (within the two hour time limit), direct the donor to attempt to provide another specimen. If the donor can provide sufficient quantity of specimen, continue the collection process. The collector may use the original custody and control form from the first attempt.

5. Annotate (time) each subsequent collection attempt in the remarks section of the custody and control form which was initiated after the first attempt.

6. If <u>after</u> a period of two hours (from the time the donor <u>first</u> <u>demonstrated</u> that he/she was unable to provide a sufficient quantity of specimen), the donor is still unable to provide an adequate specimen, <u>testing must be discontinued</u>, and the employer notified of the shy bladder situation. (Two hours is the <u>maximum</u> time permitted under DOT regulations.) The employer notifies the MRO of the situation and the MRO shall then refer the individual for a medical evaluation to develop pertinent information concerning whether the donor's inability to provide a specimen is genuine or constitutes a refusal. (In a collection for a pre-employment test, if the employer chooses not to hire the applicant, the MRO does not need to make this referral.)

7. Copies of the custody and control form (with shy bladder annotation in the remarks section) should be sent to the appropriate individuals (employer, MRO, donor, collector). Laboratory copies should be destroyed, and not left at the collection site.

Section IX - Direct Observation Collections

A collector must directly observe (i.e., accompany the donor into the stall or toilet area and observe the act of urination) a collection only under very specific circumstances. A direct observation collection must be conducted by a collector of the same sex as the donor even if the collector is an individual with medical training or background.

Required:

The DOT regulations require an immediate second collection under direct observation in the following two circumstances:

1. The donor has provided a specimen that falls outside the acceptable temperature range (32^{o}-38^{o}C/90^{o}-100^{o}F), and:

   a. Donor refuses to provide measurement of body temperature, or

   b. The body temperature varies by more than 1^{o}C/1.8^{o}F from the temperature of the specimen.

2. The collector observes conduct clearly and unequivocally indicating an attempt to substitute or adulterate the sample (i.e., substitute urine in plain view, blue dye in specimen presented, adulterated substance in view, etc.).

> In both of the above described circumstances the collector must obtain, in advance of the direct observation collection, the review and concurrence of the collector's supervisor or the designated employer representative that the facts support the determination that conditions listed in paragraph 1 or 2 exist. If concurrence is obtained, the DOT rule requires that an observed collection be conducted immediately.

Permissive:

The DOT regulations permit a urine specimen collection to be collected under direct observation when the collector is notified of this requirement by the MRO or the employer. 49 CFR Part 40 (40.25) authorizes direct observation only under the following additional two conditions:

1. The last specimen provided by the donor (i.e., on a previous DOT-mandated drug test) was determined by the laboratory to have a specific gravity of less than 1.003 and a creatinine concentration below 0.2g/L dilute specimen).

2. The donor had a verified positive result on a previous DOT drug test and is subject to return to duty or follow-up testing under DOT regulations.

In addition, DOT guidance (December 7, 1993) established that when a specimen was reported by the laboratory as not suitable for testing and the MRO has determined based on the required interview with the donor that no medical explanation exists for the specimen's unsuitability, the MRO should inform the employer that another collection under direct observation is required.

In the above cases, the decision to conduct a direct observation collection during a subsequent collection is made by the employer, not the collection site personnel. In these cases, it is the responsibility of the employer to notify the collection site personnel when a direct observation collection is warranted.

If a specimen (negative or positive) is reported by the laboratory as having creatinine and specific gravity levels below the prescribed levels, the rule does not authorize the MRO or employer to direct the employee to immediately provide another specimen for analysis. It only allows for any future collection (when a triggering event occurs, e.g., qualifying accident, random selection, etc.) to be taken under direct observation at the employer's option. A perceived dilute specimen may not be used to trigger a reasonable cause/suspicion test.

CHAIN OF CUSTODY DOCUMENTATION FOR DIRECT OBSERVATION COLLECTIONS

There may be instances in which the collector may not be able to serve as a direct observer. One example would be when the sex of the collector is different from that of the donor. In these instances, it becomes necessary for the collector to call upon another individual to act as the direct observer. When this occurs, it affects how the chain of custody block of the drug testing custody and control form must be completed.

Whenever the direct observer is not the same person as the collector, the direct observer can be included in the chain of custody block as the person who receives the specimen from the donor. When the specimen is turned over to the collector for processing, it is the direct observer who releases the specimen to the collector. To keep the chain of custody intact, the direct observer may be listed on the chain of custody block as having received

the specimen from the donor and releasing it to the collector even if the direct observer never actually physically handled the specimen. If the observer is not included in the chain of custody block, then as a minimum, the use of an observer (include reason for observed collection and name of observer) should be noted in the remarks section of the custody and control form.

In all cases, the collector should annotate in the remarks section that the collection was a direct observation collection.

Section X - What If.....

1. Only a public restroom is available for a specimen collection?

A. A public restroom may be used in the collection of DOT specimens provided it has been secured during the collection process as specified in Section II.

2. The collector doesn't have any bluing agent or the toilet does not have a bowl or tank water supply?

A. Instruct donor not to flush the toilet. Use other materials to color the water if possible (e.g., ink, food coloring, etc). Cut off the water supply during each collection; turn on for flushing of the toilet after each collection. If materials other than a bluing agent are used, the resultant color should <u>not</u> be yellow or orange and if other than blue, the collector should annotate in the remarks section the color that was actually substituted for the bluing agent.

3. The temperature sensing device or thermometer is inoperative?

A. Use an alternative temperature sensing devise, if available. If not, record in the remarks section that the temperature devise is inoperative. If the specimen bottle "feels" within normal range, process the specimen; if not, contact the collector's supervisor and annotate the circumstances in the remarks section.

4. The collector (or donor) accidentally spilled the specimen before it was sealed in the specimen bottle?

A. The collector should attempt another collection using a new collection kit (collection container, bottles, etc.).

5. The Donor does not have a photo I.D. and there is no employer representative available to positively identify the donor?

A. If the donor cannot be positively identified by a photo I.D. or by an employer representative, the collector should follow the same procedures that are used for a self-employed donor: If the donor is self-employed and has no photo identification, the collector should notify the collection site supervisor and record in the remarks section that positive identification is not available. Request the donor to provide two items of identification bearing his/her signature. Proceed with the collection. When the donor signs the certification statement, compare the donor signature with signatures on the identification

presented earlier. If the signatures appear consistent, continue to process the specimen. If the signature does not match the signatures on the identification presented, make an additional note in the remarks section stating that "signature identification is unconfirmed."

6. Donor refuses to provide his/her social security number?

A. Request that the donor provide an alternate donor identification number (e.g., badge number, pay roll number, etc.). If the donor does not provide an I.D. number, record "donor refuses to provide I.D. number" in the remarks section. This is not a fatal flaw nor a refusal if the donor subsequently provides a specimen. Proceed with the collection.

7. The clinic or office policy requires "patients" to "strip" and wear a hospital gown?

A. Except for collections conducted as a part of a required DOT physical examination which requires disrobing, DOT collections shall not require or allow disrobing.

8. The donor refuses to wash his/her hands prior to the collection?

A. Record that the donor refused to wash his/her hands in the remarks section and proceed with the collection.

9. The collection is taking place in a multi-use restroom with stalls and the collector is not the same sex as the donor?

A. After ensuring that the restroom has been secured for the collection, a collector of the same sex as the donor, or a medically certified or licensed collector of either sex, can monitor the collection from outside the stall. If the collector is not medically certified or licensed, he/she must remain outside the restroom door during the collection.

10. The donor provides a specimen less than 45 ml of volume (30 ml in a single specimen collection), leaves the collection site to drink fluids and returns to attempt another void?

A. The donor must remain within visual control of the collector, the collector's supervisor, or a company representative. This is to ensure that the donor is not allowed to leave the collection site to obtain a clean specimen, drink excessive fluids, or perform other actions that could compromise the

integrity of the specimen. If the donor leaves the collection area after he/she was told to remain at the site, this may be considered a refusal.

11. The donor provides a 30 ml specimen, but under DOT rules the employer requires a split specimen collection (45 ml) and the donor wants to remain at the collection site to attempt a second void?

A. The decision to collect split specimens is made by the employer not the donor in the pipeline and maritime industries (all other DOT operating administrations must use split specimen collection procedures). If the employer policy is to conduct split collections and the donor only produces 30 ml, this is considered insufficient quantity and an immediate new collection (void) must be initiated. Under no circumstances is the collector permitted to collect and add or combine a specimen from two separate voids.

12. The collector suspects that the specimen has been adulterated or substituted and contains less than 45 ml of volume?

A. Record in the remarks section that the specimen is adulterated and process the specimen for shipment to the laboratory regardless of the quantity. Obtain the concurrence from the collection site supervisor or company representative that conditions exist to obtain the second specimen under direct observation.

13. The collector gives the specimen bottle (after being sealed) to another individual at the collection site for preparation for shipment? Does this effect chain of custody procedures?

A. Anyone who handles or has custody of the specimen prior to the specimen bottle and the custody and control form being sealed in the shipping container must sign and date the chain of custody block on the custody and control form.

14. The donor refuses to sign the custody and control form or initial the bottle labels/seals?

A. Make the appropriate comment(s) in the remarks section of the custody and control form and continue the collection process. Refusal to sign the custody and control form or refusal to initial the bottle labels/seals is not a fatal flaw if the collector annotates this in the collection remarks section.

15. The specimen temperature is "out of range" and a second specimen has been collected under direct observation; what happens to the "first" specimen?

A. Mark the custody and control form of the first specimen indicating the specimen was out of temperature range and record in the remarks section that a second specimen was collected under direct observation. In the remarks section of the second specimen (direct observation) indicate that the specimen was

conducted under direct observation. Send both specimens and their accompanying paperwork to the laboratory, in one packet or shipping container if possible.

16. The donor has an indwelling catheter or other medical device and cannot provide a freshly voided specimen?

A. If a freshly voided specimen cannot be obtained, the collection should not be conducted. Notify the employer representative immediately of the inability to conduct the specimen collection.

17. The specimen is being stored prior to shipment?

A. If the specimen bottles have been sealed in a shipping container, the package should be stored in a secure place (preferably refrigerated if storage for several days is anticipated). The use of a log book or other documentation is recommended to track specimen storage and shipment.

18. The clinic policy requires donors to list any medications they are currently taking?

A. Listing of medications or other medical information in conjunction with the specimen collection is not permitted under the DOT regulations. The donor may record such information on the donor copy of the custody and control form or on another piece of paper that the donor retains for his/her own use.

19. The clinic requires the donor to sign a consent form?

A. The collection facility or laboratory (but not an employer site) may use a donor consent form in conjunction with the specimen collection. However, such consent form shall not indemnify or "hold harmless" the collection site or laboratory. If the donor refuses to sign the consent form, the collection facility/clinic or the employer must have procedures in place to accomplish the collection within a reasonable time. The collection cannot be postponed to another day. Refusal by the donor to sign the consent form cannot be interpreted as refusal to provide a specimen. Use of a consent form by the employer is not authorized under the DOT regulations.

20. The instructions provided with the custody and control form or specimen collection kit are different from those outlined in the DOT regulations?

A. Follow the DOT specimen collection procedures as required in 49 CFR Part 40. Notify the laboratory, if possible, that the collection was conducted

under the provisions of 49 CFR Part 40, or so note in the remarks section of the custody and control form. Inform the laboratory that the procedures that accompanied the kit do not match those contained in 49 CFR Part 40.

21. The donor asks for the collector's identification?

A. Under the DOT regulation, the collector is required to provide appropriate identification when asked to do so by the donor. Although it is good practice, there is no requirement that this be a picture ID. There is also no requirement to have the collector's business address or indicate level or extent of the collector's training in DOT specimen collection procedures on the collector's identification.

22. The donor requests to keep his/her wallet on his/her person during the collections?

A. The donor may keep his/her wallet during the specimen collection process.

23. The donor requests to have a union or legal representative present during the collection?

A. If the employer's policy permits such practice, it is permissible, as long as the union or other representative does not disrupt or interfere with the collection process or cause any delay in the collection process. Any representative must remain outside the stall or restroom when the donor is providing the specimen and should not "participate" in any way in the collection process itself.

24. The collector leaves the specimen bottles unattended and unsecured (not swealed) prior to placing it in the shipping container?

A. The integrity and security of the specimen is compromised. The collection is nullified. Discard the specimen and destroy the paperwork. Notify employer representative immediately and obtain instructions. Begin the collection process again if practicable (donor cannot be recalled).

25. Two donors request to provide their specimens at the same time in a multi-use restroom?

A. Only one donor at a time may be processed for a DOT specimen collection. One of the donors must wait until the other donor's specimen collection process is complete.

26. The donor tells the collector he/she cannot provide a specimen; when does the two hour "shy" bladder procedure start?

A. If the donor tells the collector when he/she reports for a collection that he/she cannot provide a specimen, the collector should continue the collection process and request the donor to try to provide a specimen. In many cases, the donor may, in fact, be able to provide the minimum quantity required. If the donor attempts to urinate, but comes back with no specimen or less than the required quantity, the collector should inform the donor and annotate on the form that a shy bladder condition exists and "start the clock." The added advantage of this procedure is that the collector will have documentation of an attempted collection and the time that it was attempted. The collector must ensure that the donor clearly understands when the "two hour clock" starts.

27. The collection site only has the old six (6) part custody and control form and a split specimen collection is required?

A. Split specimen collections under DOT authority cannot be collected with a six part form. Do not start the collection process, but notify the collection site supervisor or the company representative. If possible, obtain the right form.

28. The employer policy (pipeline and maritime industries under DOT rules) permits single specimen collection, but the collector only has the seven (7) part custody and control form?

A. The collector can perform DOT collection for single specimen using the seven (7) part form; Copy 3 - Split Sample, is discarded by the collector and the single collection box on the custody and control form is checked. All discarded copies of the custody and control forms and other collection supplies (used collection containers, discarded bottles, etc.) should be taken by the collector off site for disposal. Note that after February 19, 1995, collectors can use only the DOT seven part custody and control form.

29. The donor is not present when the collector seals the shipping container?

A. Only the tamper-evident seal placed on the specimen bottles must be affixed in the donor's presence. The donor's initials on the bottle labels/seals and signature on the chain of custody form attest to the accuracy of the information and the correctness of the collection process to this point. The donor does not have to be present when the specimens are prepared for shipment to the laboratory.

30. The collector wants to use a "code" name or pseudonym on the chain of custody form?

A. The use of a "code" name, pseudonym, collector I.D. number, or other substitute for the collector's real name is not acceptable. The collector's name should be the same as that appearing on the identification each collector is required to make available upon the donor's request. (The use or lack of a middle initial does not invalidate the collection).

31. The collection container and the bottles are pre-packaged in the same container (i.e., wrapped together)?

A. Current regulations require that the specimen bottles and the collection container be prepackaged or wrapped to increase donor confidence in the collection process. DOT recommends that the collection container and bottles be wrapped separately and that only the collection container be unwrapped and given to the donor. If the collection container and the bottles are wrapped together, the collector should give both the collection cup and the bottles and caps/lids (after they are unwrapped) to the donor to take to the restroom. However, the collector should ensure that the donor understands that the specimen is to be provided into the collection cup and not the bottles. The purpose of this procedure is to prevent the potential claim by the donor that the unwrapped bottles or caps, when left with the collector, could have been contaminated or otherwise compromised.

32. The collector retains the unwrapped bottles and gives the donor only the collection cup. Is this a fatal flaw?

A. No, provided the collector can provide a signed statement or other documentation indicating the unwrapped bottles were in the collector's control at all times and that there was no opportunity for anyone else to have access to them. If the bottles were left unattended, then this may provide sufficient grounds for the donor to challenge the test results related to this collection.

33. The collector failed to mark/annotate that the temperature was within range on the custody and control form (after the specimen bottles were sealed and placed in the shipping container)?

A. The collector should note this discrepancy in a log book and/or annotate it in the remarks section of the collector's copy of the custody and control form. Upon request by the MRO, the collector should provide a signed statement to the MRO explaining the situation. This is not, in itself, a fatal flaw.

34. The collector inadvertently collects a split specimen when a split specimen was <u>not</u> required (pipeline/maritime industries)?

A. This is <u>not</u> a fatal flaw. If the collector discovers that the split was collected inappropriately, he/she may discard the split specimen if it has not been sealed in the shipping container. This should be annotated in the remarks section on the custody and control form for the MRO's benefit, should the donor subsequently bring this up as a collection issue/problem. If the specimen bottles are already sealed in the shipping container the collector should annotate the circumstances of this collection on his/her copy of the custody and control form in case the MRO later questions the collection process.

35. The donor goes into the restroom and does not come out?

A. In general, the collector should tell the donor that if he/she cannot provide a specimen within five to ten minutes, that the donor should come out of the restroom and inform the collector of the inability to provide a specimen. If a donor remains in the restroom an excessive length of time (15 minutes or more), the collector should knock on the door and request the donor to come out. The collector should try to solicit some type of response from the donor that would indicate that the donor heard the collector's request.

36. The donor provides a specimen that appears to have been adulterated and departs the collection site before the required observed collection is conducted?

A. If the collector (with concurrence of the collection site supervisor or the designated employer representative) determines that an observed collection is required <u>and</u> unequivocally indicates this to the donor and the donor leaves the site, this may be considered a refusal by the employer. If the donor leaves the site prior to the collector indicating that an observed collection must be conducted, the donor should be recalled as soon as possible for the observed collection.

NOTES

(DOT has a very limited number of copies of these guidelines available. The procedures guidelines can be reproduced locally. Additional copies can be obtained from the specific operating administrations, e.g., FAA, FHWA. Copies of these procedures are also available on the FHWA (2400 baud line 202 366-3764; 9600 baud line 202 366-3175) and FTA (up to 14,400 baud 1-800 231-2061) electronic bulletin boards. DOT is in the process of also developing procedural guidelines for breath alcohol testing and general guidance for substance abuse professionals (SAP). A complete package of these procedures will be available in the near future from the Government Printing Office.)